

Food and Drug Administration, HHS

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are used in the diagnosis and treatment of propoxyphene use or overdose or in monitoring levels of propoxyphene to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3750 Quinine test system.

(a) *Identification*. A quinine test system is a device intended to measure quinine, a fever-reducing and pain-relieving drug intended in the treatment of malaria, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of quinine overdose and malaria.

(b) *Classification*. Class I.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21450, June 8, 1988; 65 FR 2310, Jan. 14, 2000]

§ 862.3830 Salicylate test system.

(a) *Identification*. A salicylate test system is a device intended to measure salicylates, a class of analgesic, antipyretic and anti-inflammatory drugs that includes aspirin, in human specimens. Measurements obtained by this device are used in diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3840 Sirolimus test system.

(a) *Identification*. A sirolimus test system is a device intended to quantitatively determine sirolimus concentrations in whole blood. Measurements are used as an aid in management of transplant patients receiving therapy with sirolimus.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Sirolimus Test Systems." See § 862.1(d) for the availability of this guidance document.

[69 FR 58259, Sept. 30, 2004]

§ 862.3850 Sulfonamide test system.

(a) *Identification*. A sulfonamide test system is a device intended to measure sulfonamides, any of the antibacterial drugs derived from sulfanilamide, in human specimens. Measurements obtained by this device are used in the di-

agnosis and treatment of sulfonamide overdose and in monitoring sulfonamide levels to ensure appropriate therapy.

(b) *Classification*. Class I.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21450, June 8, 1988; 65 FR 2310, Jan. 14, 2000]

§ 862.3870 Cannabinoid test system.

(a) *Identification*. A cannabinoid test system is a device intended to measure any of the cannabinoids, hallucinogenic compounds endogenous to marijuana, in serum, plasma, saliva, and urine. Cannabinoid compounds include *delta*-9-tetrahydrocannabinol, cannabidiol, cannabinal, and cannabichromene. Measurements obtained by this device are used in the diagnosis and treatment of cannabinoid use or abuse and in monitoring levels of cannabinoids during clinical investigational use.

(b) *Classification*. Class II.

§ 862.3880 Theophylline test system.

(a) *Identification*. A theophylline test system is a device intended to measure theophylline (a drug used for stimulation of the muscles in the cardiovascular, respiratory, and central nervous systems) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of theophylline overdose or in monitoring levels of theophylline to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3900 Tobramycin test system.

(a) *Identification*. A tobramycin test system is a device intended to measure tobramycin, an aminoglycoside antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3910 Tricyclic antidepressant drugs test system.

(a) *Identification*. A tricyclic antidepressant drugs test system is a device intended to measure any of the tricyclic antidepressant drugs in serum. The tricyclic antidepressant

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drugs include imipramine, desipramine, amitriptyline, nortriptyline, protriptyline, and doxepin. Measurements obtained by this device are used in the diagnosis and treatment of chronic depression to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3950 Vancomycin test system.

(a) *Identification*. A vancomycin test system is a device intended to measure vancomycin, an antibiotic drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.

(b) *Classification*. Class II.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

Subpart A—General Provisions

Sec.

864.1 Scope.

864.3 Effective dates of requirement for pre-market approval.

864.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Biological Stains

864.1850 Dye and chemical solution stains.

864.1860 Immunohistochemistry reagents and kits.

Subpart C—Cell and Tissue Culture Products

864.2220 Synthetic cell and tissue culture media and components.

864.2240 Cell and tissue culture supplies and equipment.

864.2260 Chromosome culture kit.

864.2280 Cultured animal and human cells.

864.2360 Mycoplasma detection media and components.

864.2800 Animal and human sera.

864.2875 Balanced salt solutions or formulations.

Subpart D—Pathology Instrumentation and Accessories

864.3010 Tissue processing equipment.

864.3250 Specimen transport and storage container.

864.3260 OTC test sample collection systems for drugs of abuse testing.

864.3300 Cytocentrifuge.

864.3400 Device for sealing microsections.

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864.3600 Microscopes and accessories.

864.3800 Automated slide stainer.

864.3875 Automated tissue processor.

Subpart E—Specimen Preparation Reagents

864.4010 General purpose reagent.

864.4020 Analyte specific reagents.

864.4400 Enzyme preparations.

Subpart F—Automated and Semi-Automated Hematology Devices

864.5200 Automated cell counter.

864.5220 Automated differential cell counter.

864.5240 Automated blood cell diluting apparatus.

864.5260 Automated cell-locating device.

864.5300 Red cell indices device.

864.5350 Microsedimentation centrifuge.

864.5400 Coagulation instrument.

864.5425 Multipurpose system for in vitro coagulation studies.

864.5600 Automated hematocrit instrument.

864.5620 Automated hemoglobin system.

864.5680 Automated heparin analyzer.

864.5700 Automated platelet aggregation system.

864.5800 Automated sedimentation rate device.

864.5850 Automated slide spinner.

864.5950 Blood volume measuring device.

Subpart G—Manual Hematology Devices

864.6100 Bleeding time device.

864.6150 Capillary blood collection tube.

864.6160 Manual blood cell counting device.

864.6400 Hematocrit measuring device.

864.6550 Occult blood test.

864.6600 Osmotic fragility test.

864.6650 Platelet adhesion test.

864.6675 Platelet aggregometer.

864.6700 Erythrocyte sedimentation rate test.

Subpart H—Hematology Kits and Packages

864.7040 Adenosine triphosphate release assay.

864.7060 Antithrombin III assay.

864.7100 Red blood cell enzyme assay.

864.7140 Activated whole blood clotting time tests.

864.7250 Erythropoietin assay.

864.7275 Euglobulin lysis time tests.

864.7280 Factor V Leiden DNA mutation detection systems.

864.7290 Factor deficiency test.

864.7300 Fibrin monomer paracoagulation test.

864.7320 Fibrinogen/fibrin degradation products assay.

864.7340 Fibrinogen determination system.